

NEW YORK STATE DEPARTMENT OF HEALTH

Smallpox Vaccination Side Effects

The smallpox vaccine prevents smallpox. For most people, it is safe and effective. Most people experience normal, typically mild reactions to the vaccine, which indicate that it is beginning to work.

Some people may experience reactions that may require medical attention.

Normal, Typically Mild Reactions

These reactions usually go away without treatment:

- The arm receiving the vaccination may be sore and red where the vaccine was given.
- The glands in the armpits may become large and sore.
- The vaccinated person may run a low fever.
- One out of 3 people may feel bad enough to miss work, school, or recreational activity or have trouble sleeping.

Serious Reactions

In the past, about 1,000 people for every 1 million people vaccinated for the first time experienced reactions that, while not life-threatening, were serious. These reactions may require medical attention:

A vaccinia rash or outbreak of sores limited to one area. This is an accidental spreading of the vaccinia virus caused by touching the vaccination site and then touching another part of the body or another person. It usually occurs on the genitals or face, including the eyes, where it can damage sight or lead to blindness. Washing hands with soap and water after touching the vaccine site will help prevent this (inadvertent inoculation).

A widespread vaccinia rash. The virus spreads from the vaccination site through the blood. Sores break out on parts of the body away from the vaccination site (generalized vaccinia).

A toxic or allergic rash in response to the vaccine that can take various forms (erythema multiforme).

Life-Threatening Reactions

Rarely, people have had very bad reactions to the vaccine. In the past, between 14 and 52 people per 1 million people vaccinated for the first time experienced potentially life-threatening reactions. These reactions require immediate medical attention:

- **Eczema vaccinatum.** Serious skin rashes caused by widespread infection of the skin in people with skin conditions such as eczema or atopic dermatitis.
- Progressive vaccinia (or vaccinia necrosum). Ongoing infection of skin with tissue destruction frequently leading to death.
- Postvaccinal encephalitis. Inflammation of the brain.

People with certain medical conditions—including people with weakened immune systems or certain skin conditions—are more likely to have these reactions and should not get the smallpox vaccine unless they have been exposed to smallpox.

Careful monitoring of smallpox vaccinations given over recent months has suggested that the vaccine may have caused side effects on the heart. There have been reports of heart pain (angina), heart inflammation (myocarditis), inflammation of the membrane covering the heart lining (pericarditis), and/or a combination of these two problems (myopericarditis). Experts are exploring this more in depth. As a precaution, if you have been diagnosed by a doctor as having a heart condition with or without symptoms you should NOT get the smallpox vaccine at this time. These include conditions such as known coronary disease and/or three or more of the following risk factors:

- You have been told by a doctor that you have high blood pressure.
- You have been told by a doctor that you have high blood cholesterol.
- You have been told by a doctor that you have diabetes or high blood sugar.
- You have a close relative (mother, father, brother, or sister) who had a heart condition before the age of 50.
- You smoke cigarettes now.

Based on past experience, it is estimated that between 1 and 2 people out of every 1 million people vaccinated may die as a result of life-threatening reactions to the vaccine.

Important Note: Statistical information about smallpox vaccine adverse reactions is based on data from two studies conducted in 1968. Adverse event rates in the United States today may be higher because there may be more people at risk from immune suppression (from cancer, cancer therapy, organ transplants, and illnesses such as HIV/AIDS) and eczema or atopic dermatitis. The outcome associated with adverse events may be less severe than previously reported because of advances in medical care. Rates may be lower for persons previously vaccinated.

FOR MORE INFORMATION, VISIT: www.health.state.ny.us
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